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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,367	01/23/2002	Michael Affolter	112843-029	4325
29174	7590	06/27/2007		
BELL, BOYD & LLOYD, LLC			EXAMINER	
P. O. BOX 1135			KAM, CHIH MIN	
CHICAGO, IL 60690-1165			ART UNIT	PAPER NUMBER
			1656	
			MAIL DATE	DELIVERY MODE
			06/27/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/936,367

Applicant(s)

AFFOLTER ET AL.

Examiner

Chih-Min Kam

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1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 9-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7 and 14-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/19/06</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The Request for Continued Examination (RCE) filed on May 10, 2007 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

#### ***Status of the Claims***

2. Claims 1-7 and 9-18 are pending.

Applicants' amendments filed March 12 and May 10, 2007 are acknowledged.

Applicants' response has been fully considered. Claims 7 and 16-18 have been amended, and claim 8 has been cancelled. Claims 1-6 and 9-13 are non-elected inventions and withdrawn from consideration. Therefore, claims 7 and 14-18 are examined.

#### **Withdrawn Informalities**

3. The previous objection to the specification regarding the Sequence Listing, is withdrawn in view of applicant's submission of a paper copy and CRF of Sequence Listing filed March 12, 2007, and applicants' response at page 5 in the amendment filed May 10, 2007.

#### **Withdrawn Claim Objections**

4. The previous objection to claim 16, is withdrawn in view of applicant's amendment to the claim, and applicants' response at page 5 in the amendment filed May 10, 2007.

#### **Withdrawn Claim Rejections - 35 USC § 112**

5. The previous rejection of claims 7, 8 and 14-18 under 35 U.S.C. 112, first paragraph, written description, is withdrawn in view of applicants' amendment to the claim, applicants' cancellation of the claims, and applicants' response at pages 5-6 in the amendment filed May 10, 2007.

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6. The previous rejection of claim 8 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' cancellation of the claim in the amendment filed May 10, 2007.

***New Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 7, 14 and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 7, 14 and 16-18 are directed to a method for enhancing the proteolytic activity of a koji mold belonging to the genus *Aspergillus*, *Rhizopus*, *Mucor*, or *Penicillium*, comprising modifying a *creA* gene of the koji mold such that the gene product thereof is essentially nonfunctional; or a method for preparing a protein hydrolysate by hydrolyzing a proteinaceous materials with a Koji mold belonging to the genus *Aspergillus*, *Rhizopus*, *Mucor*, or *Penicillium*, comprising modifying a *creA* gene of the koji mold such that the gene product thereof is essentially nonfunctional.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other

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materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

While the specification describes the creA gene can be specifically modified (e.g., creA gene being deleted) such that a non-functional gene product can be obtained and would not block the transcription of protease, and a creA mutation may be combined with an increased production of the areA gene, a positive stimulator for the production of protease (pages 4-5), the specification does not disclose a genus of variants for a modified creA gene of the koji mold having a non-functional gene product. A specific modification of creA gene such as N-terminal of DNA binding zinc finger domain being truncated (Example 3) and creA gene being deleted (Example 4) do not sufficiently describe a genus of modified creA genes encoding non-functional gene products, where the function of the gene product is not specified. Without guidance on the structure/activity correlation of creA gene variants, one skilled in the art would not know which modified creA gene encodes a nonfunctional gene product. The lack of description of the structure/activity correlation of creA gene variants in a koji mold and the lack

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of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

***Maintained Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 7 and 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 7 and 14-17 are indefinite because the claims lack an essential step in the method for enhancing the proteolytic activity of a koji mold. The omitted step is the outcome of the process, it is not clear whether the modification of creA gene of the koji mold resulting the non-functional gene product would enhance the proteolytic activity of a koji mold or not. It is not clear the term “nonfunctional” referd to what function of the gene product. Claims 14-17 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

10. Claim 18 is indefinite because the claim lacks essential method steps in the method of preparing a protein hydrolysate. The omitted steps are reacting (or hydrolyzing) proteinaceous material with a koji mold and the outcome of the process, it is not clear whether the proteinaceous material is hydrolyzed or not. . It is not clear the term “nonfunctional” referd to what function of the gene product.

Applicant does not respond to the rejection.

***Conclusion***

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Primary Patent Examiner



CHIH-MIN KAM  
PRIMARY EXAMINER

CMK

June 23, 2007